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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/662,790 | 09/15/2000 | Mark Chandler | 215063.02301 | 2090 |
| 27160 | 7590 | 12/28/2004 | EXAMINER | |
| KATTEN MUCHIN ZAVIS ROSENMAN | | | CLOW, LORI A | |
| 525 WEST MONROE STREET | | | ART UNIT | |
| CHICAGO, IL 60661-3693 | | | PAPER NUMBER | |
| | | | 1631 | |

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/662,790

Applicant(s)

CHANDLER ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 40 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response, filed 6 October 2004, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-7 and 39-41 are currently pending. Claim 39 has been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Oath

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: for inventor Mark Chandler, the signature does not include a date of signing. Correction is requested.

Priority

Priority to provisional application 60/153,941 filed 15 September 1999 remains denied for the reasons set forth in the previous Office Actions. The priority date that is granted is the filing date of 15 September 2000.

Applicants traverse this denial and state that the Provisional Application includes several passages of support. For instance, page 2, lines 5-7, which state that "...using the analysis of 200-300 biochemicals in a single sample". This is not persuasive in that these lines refer to

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blood sample use with a database and several hundred chemicals, but not a MAP (Multi-Analyte Profile) Test Panel that includes 75 or more subsets of microspheres.

Applicant further argues that page 2, lines 10-12 and 14-17 provide support for the MAP recited in the instant claims. However this is not persuasive in that these passages refer to 50 or more analytes and NOT 75 or more subsets of microspheres, which make up the MAP Test Panel.

Applicant further points to page 5, lines 14-23 for support, but again, none is found because this paragraph refers to several WO documents, and as stated in the Office Action dated 4 August 2003 and re-iterated in the Office Action dated 22 January 2004, mere reference to a document is not a proper incorporation by reference of anything (See page 6, lines 3-9 (8/4/03)). Therefore, the provisional application, which does not properly incorporate WO 99/19515 by reference, does not describe the MAP Test Panel of the instant claims.

Finally Applicant points to page 9, lines 6-12 and page 11, lines 8-15 for support. However, these paragraphs do not define the MAP Test Panel of the instant claims which comprises subsets of microspheres that are distinguishable by fluorescent signatures which are designed to selectively interact with a predetermined analyte. At best the provisional application describes multiple analyte usage. Priority remains denied.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-7, 40 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 7 recite "one reagent designed to interact selectively" with a pre-determined analyte". It is unclear as to the metes and bounds of "selectively" in the claims. Does selectively mean interaction with one and only one analyte, or some other meaning. It is clear from the originally filed claims that Applicants have different definitions for "specifically" and "selectively", however, it is not clear what Applicant intends for "selectively". Clarification is requested. Applicant is reminded that any definition must be supported by the originally filed disclosure.

Claims 1 and 7 now recite "microspheres of **the** one subset". There is insufficient antecedent basis on the claim for "the one". Which one? Clarification is requested.

Claim 2 recites "**the** subsets of the microspheres". What subset? There is insufficient antecedent basis for the subsets. Clarification is requested.

Claim 5 still recites "natural product". It is still unclear as to the limitation intended by "natural product". Applicant contends that due to the amendment of claim 1, it is clear that the natural product interacts selectively with a predetermined analyte. This does not clarify what natural product is intended. This could still be any known natural product. Clarification is again requested.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 40 and 41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kettman et al (Cytometry (1998) Vol. 33, pages 234-243), in view of Ekins et al. (Journal of Pharmaceutical and Biomedical Analysis (1989) Vol. 7, pages 155-168), for the reasons set forth in the previous Office Actions.

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Applicant argues that Kettman discloses classification and properties of 64 multiplexed microsphere sets, but does not disclose a MAP Test Panel that includes 75 or more subsets. This is acknowledged, as was set forth in the previous Office Action at page 6, line 16. This argument is not persuasive because Kettman et al. is not relied upon to teach 75 or more subsets. Eikens et al. is relied upon to teach that embodiment, as was also set forth at page 6, line 17 of the previous Office Action. As a reminder, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant further argues that Eikens et al. describes "enabling the simultaneous measurement of tens or even hundreds of substances simultaneously in the same small sample, Kettman cannot be combined with Eikens to overcome deficiencies therein. For example, Eikens does not disclose a test panel that includes any microspheres at all. Instead, Eikens describes an assay in which different antibodies are located at different places on one surface which after exposure to a sample is sensed by a laser in a procedure closely resembling the operation of data-storage devices". This is not persuasive in that Eikens et al do not have to teach microspheres. Kettman et al. have taught that embodiment and Eikens et al. are relied upon to teach that hundreds of probes are associated with fluorescence, wherein the fluorescent probes are used to detect binding reagents attached to a solid surface. Kettman et al. also teach probes (microspheres/solid surface) coupled to a reagent which are fluorescently labeled. The fact that Eikens et al. teach a method of detection is moot in view of the limitations set forth in

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the instant claims, which do not include methods of detection. Because both teach the same types of assays and for the reasons stated in the previous Office Action, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have incorporated more than 64 microspheres into the MAP Test Panel of Kettman et al., as suggested by Eikens et al. One would have been motivated to do so because Eikens et al. state that "fluorescent labels are particularly useful in this context because they readily permit arrays of different antibody microspots distributed over a surface, each directed against a different analyte, to be individually examined thus enabling multiple assays to be carried out on the same small sample (page 166, lines 16-21)".

Applicant further argues that Eikens et al. teach a different test panel and a different method of detection (flow cytometer). Again this argument is moot because Eikens et al. are relied upon for the teaching that more than 64 "probes" would have been obvious and not for the test panel itself. In addition, the claims are not directed to a method of detection, as stated above.

Finally, Applicant have not demonstrated that there is any advantage or improvement in the art by incorporating 75 or more microspheres into the MAP Test Panel, and none is apparent.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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December 22, 2004
Lori A. Clow, Ph.D.
Art Unit 1631

Lori A. Clow

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran
12/23/04